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| 09/670,529      | 09/27/2000  | Yannick Albertone    | AD6649 US NA        | 6969             |

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| EXAMINER |
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BOYD, JENNIFER A

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| ART UNIT | PAPER NUMBER |
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1771

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/670,529

Applicant(s)

ALBERTONE ET AL.

Examiner

Jennifer A. Boyd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 11 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2005 has been entered. The Applicant's Remarks and Declaration under Rule 132, filed July 12, 2005, have been entered and have been carefully considered. Claims 3 and 10 are cancelled and claims 1 – 2, 4 – 9 and 12 are pending. In view of Applicant's arguments, the Examiner withdraws all previously set forth rejections. Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

3. Claim 4 is objected to because of the following informalities: claim 4 is dependent on claim 3, which is cancelled. For the purposes of examination, the Examiner will assume that the Applicant intends for claim 4 to depend from claim 1 or 2. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

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4. Claims 1 – 2, 4 – 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavers et al. (US 4,939,009) in view of Wilfong et al. (US 5,407,713).

Beavers is directed to a multilayered sheet having excellent adhesion which is useful as a carrier for decorative and protective coating to applied to substrates (Title and column 1, lines 10 – 23). Beavers teaches using the film as a pouch for medical solutions (column 4, lines 30 – 45).

As to claim 1, Beavers teaches a laminate comprising a layer of copolyetherester and a layer of polyolefin sandwiching a tie layer (Abstract). The tie layer comprises a low molecular weight polyethylene and about 0.1 to about 30 weight percent of vinyl acetate (column 5, lines 9 – 17). The copolyetherester layer is equated to Applicant's "copolyetherester layer", the polyolefin layer is equated to Applicant's "moisture vapor control layer" and the tie layer is equated to Applicant's "tie layer".

As to claim 2, Beavers teaches that the polyolefin layer can comprise polypropylene (column 4, lines 20 – 28).

As to claim 8, Beavers teaches that the tie layer comprises a low molecular weight polyethylene and about 0.1 to about 30 weight percent of vinyl acetate (column 5, lines 9 – 17).

As to claim 9, Beavers teaches that the layer of copolyetherester only comprises copolyetherester, therefore, the content is approximately 100%.

Beavers fails to teach that a substrate comprising a woven or non-woven material is attached to the moisture vapor control layer as required by claim 1. Beavers fails to disclose that the substrate comprising a woven or non-woven material comprises polyethylene, polypropylene, polyester, or blends thereof as required by claim 6.

Wilfong et al. is directed to a multilayered barrier structure (Title). Wilfong teaches that the articles formed from the multilayered barrier structures are not limited to just the multilayered films but can be modified for specialty applications by adding additional layers thereto. For example, a specialty ostomy pouch comprising a multilayered barrier structure of the present invention could be formed by laminating a fabric backing of a woven or nonwoven material to the surface of the ostomy pouch. This fabric backing would act to provide a soft layer against a wearer's skin and thus make the ostomy pouch more comfortable and non-clinging (column 20, lines 40 – 55). Wilfong teaches that the fabric backing can be formed from polypropylene, for example (column 20, lines 55 – 65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a polypropylene woven or non-woven substrate as suggested by Wilfong adjacent to the moisture vapor control layer of the laminate film of Beavers motivated by the desire to use the film in specialty applications such as a ostomy pouch where the substrate can provide a comfortable, soft layer for use adjacent to a patient's skin.

As to claims 4 – 5, Beavers in view of Wilfong fails to disclose the moisture vapor control layer has a thickness of 1 to 5  $\mu\text{m}$  as required by claim 4 and the copolyetherester layer is from about 12 to 30  $\mu\text{m}$  and the thickness of the tie layer is about 1 to 5  $\mu\text{m}$  as required by claim 5. It should be noted that thickness is a result effective variable. Beavers notes that the thickness of the various layers can vary greatly depending on the desired properties (column 2, lines 45 –

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55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the moisture vapor control layer with a thickness of 1 to 5  $\mu\text{m}$  as required by claim 4 and the copolyetherester layer is from about 12 to 30  $\mu\text{m}$  and the thickness of the tie layer is about 1 to 5  $\mu\text{m}$  as required by claim 5 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the thickness of the layers in the laminate film to have an effectively flexible and strong laminate with the desired properties.

As to claim 7, although Beavers in view of Wilfong does not explicitly teach the claimed bond strength of at least 1 N/m, it would have been obvious to one of ordinary skill in the art to optimize the bond strength through the process of routine experimentation through such means as the selection of the components in the tie layer, process parameters, etc., in order to arrive at a strong material since these are known to be result effective variables.

As to claims 1 and 11, although Beavers in view of Wilfong do not explicitly teach the claimed MVTR inequality and ratio, it is reasonable to presume that the MVTR is inherent to the laminate structure of Mueller in view of Beavers et al. Support for said presumption is found in the use of like materials (a laminate comprising a non-woven or woven substrate layer, moisture vapor control film layer, a tie layer comprising ethylene and vinyl acetate and a copolyetherester layer) which would result in claimed MVTR inequality and ratio. The burden is upon Applicant

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to prove otherwise. In addition, the presently claimed property of MVTR inequality and ratio would obviously have been present once the Beavers in view of Mueller product is provided.

***Allowable Subject Matter***

5. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claim 12 is allowable because the prior art fails to teach or suggest adding the following layers to the structure of claim 1: an adhesive or primer adjacent to the copolyetherester layer and a second substrate layer comprising at least 50 weight percent of a polyolefin. Beavers only suggests creating three or five layered structures where the layers are configured accordingly: copolyetherester layer, tie layer of a low weight polyethylene resin and polyolefin layer *or* copolyetherester layer, tie layer of a low weight polyethylene resin, polyolefin layer, tie layer of a low weight polyethylene resin and copolyetherester layer. In order to create the laminate as claimed in claim 12, one would have to rearrange the layers of Beavers and there is no motivation for the rearrangement.

***Response to Arguments***

7. Applicant's arguments filed July 12, 2005 have been fully considered but they are not persuasive.

Applicant argues that Beavers does not teach Applicant's layer thickness. The Examiner

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has asserted that the layer thickness is a result effective variable and it would be obvious to optimize based on the desired end use. Applicant notes that Beavers states that the layered films range in thickness from 3 – 4 mils (75 – 100 microns) up to 50 mils (1.25 mm). The Examiner agrees with this statement, however, it should be noted that Beavers teaches that the *total* thickness is 3 – 4 mils, not the thickness of the individual layers. In fact, Beavers teaches that the thickness of the individual layers can vary greatly depending on the desired properties (see Beavers, column 2, lines 50 – 55). The Examiner submits that the Beavers statement provides motivation to optimize the thickness of the individual layers and renders Applicant's invention obvious. If the claimed ranges have unexpected results, the burden is upon the Applicant to demonstrate that the claimed ranges are not a matter of simple optimization. The Examiner highly suggests to the Applicant to submit a 37 CFR 1.132 Declaration to establish unexpected results. In the Declaration, the Applicant should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960) and must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. It should be noted that the Applicant has submitted a Declaration under Rule 132 to attempt to establish unexpected results in respect to thickness of the moisture vapor control layer. The Applicant performed an experiment in attempts to demonstrate the effects on the MVTR by varying the thickness of the moisture vapor control layer. The Examiner has not given the Declaration weight because the Applicant has failed to compare the instant invention with Beavers. Furthermore, in Applicant's attempt to establish that the MVTR is determined by the thickness of the moisture vapor control layer, the Applicant does not prove that Beavers would not meet the MVTR inequality as



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required by claim 1. If the thickness of the moisture vapor control layer is critical, the Examiner suggests incorporating the limitation into claim 1. The Applicant indicates that the claimed MVTR ratio can be maintained over the range of film structures that are of interest. Likewise, Applicant has not provided evidence that Beavers would not meet Applicant's ratio claim. If the MVTR ratio is critical, the Examiner suggests incorporating the limitation into claim 1.

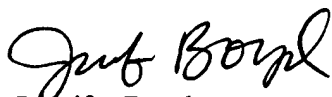
Applicant argues that the thickness that is taught by Beavers would lead to very small, and possibly unmeasurable values of MVTR for which asymmetry would have no significance. Applicant does not provide evidence in support of this argument. "Mere lawyers' arguments unsupported by factual evidence are insufficient to establish unexpected results." *In re Linder*, 173 USPQ 356. See also *In re Wood*, 199 USPQ 137. Since there is no evidence on record establishing that the thickness as taught by Beavers would lead to very small and possibly unmeasurable values of MVTR, the rejection is maintained. Furthermore, it should be noted that claim 1 only requires that  $MVTR_{CAS} > MVTR_{SAC}$ . Even if  $MVTR_{CAS}$  and  $MVTR_{SAC}$  have very small values as suggested by Applicant, as long as  $MVTR_{CAS}$  is slightly larger than  $MVTR_{SAC}$ , the claim limitations of claim 1 are met.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Boyd  
September 13, 2005



**Ula C. Ruddock**  
Primary Examiner  
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